

Questions to Banksia:

1. How is the distribution of the 40 participants across the 7 locations

The enrolment will be competitive . We have no preference of site or pre-allocation of patients / site

2. Is it possible to have more than 40 participants?

As of now BANKSIA is capped at 40 patients . However, based on data and emerging trends we might internally decide to alter number of participants.

3. Is there a chance participants might be excluded by lottery, or that participants from, for example, the Netherlands might need to travel to Germany? (A few of them are happy to fly to neighbouring country or even Australia to be able for the trials.

We may be open to patients travelling to nearest convenient sites in Europe to enrol in the Natural History Study.

4. Is the qualification criterion for percentage of vision with or without correction (glasses/contact lenses)?

The qualifying criteria is WITH correction.

Questions to Sundew:

1. Can people from the Netherlands also participate in Sundew?

Yes, we are making travel arrangements for participants from outside of Australia to fly in to participate in Sundew. In parallel we are also checking on local regulatory requirements in Australia to support international

2. There is one person that would fly to Australia for this. I have a contact information of the patient who would like to fly to Australia with no condition, please let me know how you would like me to share the contact information. Many more would like to do the same if there are less visits, so they have a follow up question below

I have been receiving and responding to such requests in detail from the SUNDEW mailbox. So please request them to email us at

SUNDEW@pyctx.com

3. if it is possible that people from Netherlands can fly to Australia for a trial, how would it likely to be e.g. First session in Australia and follow-up sessions in Amsterdam? What's the travel arrangement: how long would one need to stay in Australia for a visit?

Unfortunately, intervention visit as well as all followup visit will be in Australia for now. Please feel free to share the following information.

<https://clinicaltrials.gov/study/NCT06461286>

Are you able to travel to Australia to participate in the trial ?

You will be reimbursed for any reasonable travel, accommodation, parking, meals and other expenses associated with the research project visits.

At a high level, participation will involve 4 trips to Australia over a 1year period till the end of the study.

Trip options are as below :

1. 1st Trip for 14 days, involving 5 clinic visits – screening, baseline, dosing , observation (2) OR

2. 1st Trip for 30 days, involving 7 clinic visits - screening, baseline, dosing , observation (4)

This will be followed by 3 other trips at 3month, 6month and 12month visit to study end. Each of these trips will be for a week involving 1 clinic visit.

If you are interested to participate, following will be the steps to enrollment.

- **Prescreening** : Please connect us to your Neuroophthalmologist, so we can share our study protocol with him/her so you can get pre-screened for your eligibility to participate in our study , which will include a genetic screening to determine what is the mutation that is driving your disease. Our study can only include patients with OPA1 mutation associated ADOA. If you already know your OPA1 mutation status and your test is from an accredited genetic testing lab, it will save some wait time in the screening phase.
- **Consent** : Once you give us permission, we will put you in touch with the Study coordinator : sundew.mrg.coordinator@groups.sydney.edu.au , so they can send you the Informed Consent Form to review. If you have questions, you can reach out to our Principal Investigator Dr. Clare Fraser at Sydney Eye Hospital at clare.fraser@sydney.edu.au
- **Travel** : Once you are committed to participate, we will connect you to our travel partner, to assist you with planning your travel and stay. You will need to sign the Informed Consent Form, on-site in Sydney for official enrollment into SUNDEW, which will be followed by your baseline visit and dosing.